## WISEWOMAN Program

Guidance and Resource Document July 2008

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## **Abbreviations and Acronyms**

Below is a list of abbreviations and acronyms that are commonly used by the WISEWOMAN Program.

	1
5 A's	Assess, advise, agree, assist,
	and arrange
A1C Test	Glycosolated hemoglobin
	test
ADA	American Diabetes
	Association
ATP III	Adult Treatment Panel III
	Report (National Cholesterol
	Education Program, 2001)
BCCEDP	Breast and Cervical Cancer
	Early Detection Program
	(State/Tribal-level program)
BMI	Body mass index
CDC	Centers for Disease Control
	and Prevention
CLIA	Clinical Laboratory
	Improvement Amendments
CHD	Coronary heart disease
CVD	Cardiovascular disease
DASH	Dietary Approaches to Stop
	Hypertension
DBP	Diastolic blood pressure
DCPC	Division of Cancer
	Prevention and Control
DDT	Division of Diabetes
	Translation
DHDSP	Division for Heart Disease
	and Stroke Prevention
DHHS	Department of Health and
	Human Services
DNPAO	Division of Nutrition,
	Physical Activity, and
	Obesity
FPG Test	Fasting plasma glucose test

HBP	High blood pressure
HDL-C	High-density lipoprotein
	cholesterol
HTN	Hypertension
JNC 7	Seventh Report of the Joint
	National Committee on
	Prevention, Detection,
	Evaluation, and Treatment of
	High Blood Pressure
	(JNC 7, 2004)
LDL-C	Low-density lipoprotein
	cholesterol
LSI	Lifestyle intervention
MDE	Minimum data element
NBCCEDP	National Breast and Cervical
	Cancer Early Detection
	Program
NCCDPHP	National Center for Chronic
	Disease Prevention and
	Health Promotion
NCEP	National Cholesterol
	Education Program
NHLBI	National Heart, Lung, and
	Blood Institute
NIH	National Institutes of Health
OGTT	Oral glucose tolerance test
OSH	Office on Smoking and
	Health
RTI	Research Triangle Institute
SBP	Systolic blood pressure
TLC	Therapeutic lifestyle changes
WISEWOMAN	Well-integrated Screening
	and Evaluation for Women
	Across the Nation

Note: Throughout this document, when the "p" is capitalized in "Program", it is referring to the CDC WISEWOMAN Program and when it is lower case, it is referring to the CDC-funded State/Tribal programs.

#### Introduction

#### **Background**

In 1993, Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Program to extend the services that are provided to women as part of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

The mission and vision for the CDC WISEWOMAN Program are:

**WISEWOMAN Vision:** A world where any woman can access preventive health services and gain the

wisdom to improve her health.

**WISEWOMAN Mission:** Provide low-income, underinsured, or uninsured 40-64 year old women with the

knowledge, skills, and opportunities to improve their diet, physical activity, and other life habits to prevent, delay, or control cardiovascular and other chronic

diseases.

The priority population for WISEWOMAN is women aged 40-64 who are enrolled in NBCCEDP. The program provides NBCCEDP participants with access to additional preventive health services by screening for heart disease and stroke risk factors and using national clinical care guidelines to refer women to quality care. The program also provides lifestyle interventions that are tailored to each woman's heart disease and stroke risk factor screening results and her readiness to make lifestyle behavior changes.

In 2008 CDC released Funding Opportunity Announcement (FOA) DP08-804, which began a new 5-year funding cycle for the WISEWOMAN Program. The goals of the WISEWOMAN Program under the new FOA include:

- 1. Maximizing the reach of the program (i.e., provide services to as many women as possible).
- 2. Working to eliminate health disparities (by serving those most in need).
- 3. Decreasing heart disease and stroke risk factors of the WISEWOMAN population.
- 4. Maximizing the number and variety of settings that deliver WISEWOMAN services (e.g., screening, lifestyle intervention).
- 5. Ensuring that WISEWOMAN is delivered as intended (i.e., direct services are implemented with fidelity).
- 6. Sustaining the benefits of WISEWOMAN over time at the individual level (e.g., linking participants to low-cost community-based resources that support heart health) and organizational level (e.g., implementing policies and procedures that reflect a focus on primary prevention and follow national guidelines).

#### **WISEWOMAN and NBCCEDP: Similarities and Differences**

The WISEWOMAN Program and NBCCEDP share many similarities, but there are also some differences between the two programs. One of the major differences is that WISEWOMAN provides a lifestyle intervention to promote health. Specifically:

- The WISEWOMAN Program uses evidence-informed lifestyle interventions that promote a heart healthy diet and being physically active;
- Lifestyle interventions also support cardiovascular risk reduction such as encouraging participants to become tobacco-free and;
- Funded WISEWOMAN programs strive to deliver the lifestyle interventions in ways that allow participants to learn and develop new skills to improve their heart health in a culturally relevant context.

One major strength of the WISEWOMAN Program is that it shares the NBCCEDP framework which includes an established infrastructure at the State/Tribal health agency that has experience and expertise in:

- Recruiting and working with the women eligible for services.
- Delivering screening services through an established health care delivery system.
- Collecting and reporting data (minimum data elements) that are used to track, monitor, and evaluate program efforts.
- Providing professional development opportunities for staff, providers, and partners.
- Promoting the program and providing public education to raise awareness about the need for women to receive program services.
- Assuring that quality care is provided to the women participating in the program.

The table below provides an at-a-glance comparison of WISEWOMAN and NBCCEDP.

Topic	WISEWOMAN	NBCCEDP
Focus of Program	Screening and Lifestyle intervention: reducing heart disease, stroke, and other chronic disease risk factors through primary prevention (screening) and health promotion strategies (emphasizing healthful eating, being physically active, and living tobacco-free)	Screening Program: finding breast and cervical cancer as early as possible through testing
Services Provided	Heart disease and stroke risk factor screening, which must include blood pressure, cholesterol, glucose, weight, height, personal medical history, family medical history, and health behavior and readiness to change assessments  Referrals for women with abnormal screening values to health care providers for diagnostic services	Cancer screening: breast exam, Pap test, and mammography  Diagnostic tests to pinpoint problems  Referrals for women with abnormal or suspicious test results to health care providers for medical management of condition(s)

	and medical management of condition(s)  Evidence-informed lifestyle interventions tailored to different levels of heart disease and stroke risk and readiness to make lifestyle behavior changes  Links participants to free or low-cost community-based nutrition, physical activity, and tobacco cessation resources	
Year First State/Tribal Health Agency Was Funded	1995	1990
Age Group Targeted	40-64 year old women enrolled in the State/Tribal BCCEDP	18-64 year old women (cervical cancer screening) 50-64 year old women (mammography testing)
Rescreening Requirement	Conduct a rescreening on all WISEWOMAN participants who return for their BCCEDP annual exam within 12-18 months after their WISEWOMAN baseline screening.	While rescreening women is an important program priority, at this time, CDC has not established a minimum standard or performance indicator related to this activity
Number of Funded Programs	19 State and 2 Tribal Organizations	50 States, DC, 5 Territories, and 12 Tribal Organizations
Program Administration	Through CDC's Division for Heart Disease and Stroke Prevention, Program Development and Services Branch, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)*	Through CDC's Division of Cancer Prevention and Control, Program Services Branch, NCCDPHP

<sup>\*</sup> From the WISEWOMAN Program's inception until September 2005, it was administered by CDC's Division of Nutrition, Physical Activity and Obesity.

#### **Overview of the Document**

This document is designed to provide CDC-funded State/Tribal WISEWOMAN programs with information about resources and the guidance needed to develop, implement, and evaluate a WISEWOMAN program. The document is divided into four Sections that correspond to the WISEWOMAN Program's four components: Program Management, Direct Services, Evaluation, and Partnerships.

Each section includes detailed information about the WISEWOMAN Program components and includes the following categories, as applicable:

**Requirements:** Requirements from FOA DP08-804 and in WISEWOMAN legislation are

stated in this category.

**Guidance:** Suggestions and guidance for successful implementation of the topic are

included in this category.

**Monitoring:** The ways CDC staff members will monitor the State/Tribal program's

success at meeting CDC WISEWOMAN Program requirements are included

in this category.

**References:** References for resources related to the topic are included in this category.

**Key Related Topics:** Topics in this document that might provide further clarification or additional

information related to the topic are included in this category.

# Section 1 Program Management

#### 60/40 Distribution of Funds

#### **Requirements**

In accordance with Public Law 101-354 and its amendments,<sup>1</sup> at least 60% of WISEWOMAN cooperative agreement funds must be used for expenses that can be tied to an individual program participant. Costs allowable in the 60% category are those that benefit the woman directly. Examples include:

- Providing direct services (e.g., screening, risk reduction counseling, lifestyle intervention(s), diagnostic exams, case management for women with alert values, support services used to maximize participation in screening and lifestyle intervention services).
- The cost of incentives to support heart healthy behaviors.
- Providing transportation so participants can attend WISEWOMAN appointments.

No more than 40% of cooperative agreement funds can be used for services that do not directly benefit the woman. Examples include:

- Management activities
- Public education initiatives
- Professional development
- Partnerships
- Community engagement
- Establishment of methods to monitor the quality of screening procedures, risk reduction counseling, lifestyle intervention(s), and delivery of the 5 A's.<sup>2</sup> This includes data management, quality improvement, and quality assurance activities.
- Evaluation

Administrative costs, which support infrastructure activities, are considered part of the 40% budget distribution and no more than 10% of WISEWOMAN cooperative agreement funds may be used for administrative expenses.<sup>1</sup>

#### Guidance

Expenses that can be tied to an individual participant (e.g., conducting screening, providing risk reduction counseling, delivering the lifestyle intervention, cost of incentives, transportation costs) belong in the 60% category. The activities connected to these expenses are sometimes referred to as "direct services."

When developing the annual budget, State/Tribal programs should first determine how much funding is needed to deliver direct services to the number of women they propose to serve. The WISEWOMAN Direct Services Cost Worksheet<sup>3</sup> was developed to help programs identify the amount of funds that contribute to the 60% category. The numbers and amounts used in the Direct Services Cost Worksheet should match those used in the proposed budget and can be used as part of the budget narrative.

	Each line item in the proposed budget needs to indicate if the item is considered to be part of direct service delivery (60%) or not (40%). The type of activities conducted by staff should be used to determine how much time (i.e., salary) should be allocated to the 60% or 40% category.  The basis for calculating the 60/40 distribution is the total amount of Federal monies awarded to the State/Tribal program. It does not apply to the non-Federal matching funds.  The 10% limitation on administrative costs is in lieu of indirect costs. Each program may define the basis for its administrative costs. However, administrative expenses (i.e., indirect costs) associated with all contracts are considered part of the 10% limitation placed on overall total administrative costs under the cooperative agreement award.  The total dollar amount of Federal monies awarded to the State/Tribal program is the figure that should be used as the basis for determining the
	10% administrative costs. For example, if a program is awarded \$500,000, it can allocate no more than \$50,000 for administrative costs.
Monitoring	CDC staff members will review the budget, budget narrative, and other data sources to determine if the State/Tribal program is in compliance with the 60/40 requirement.
References	<sup>1</sup> Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the amendment that led to the creation of WISEWOMAN are available at <a href="http://www.cdc.gov/wisewoman/legislation_highlight.htm">http://www.cdc.gov/wisewoman/legislation_highlight.htm</a> <sup>2</sup> Additional information about the 5 A's can be found in the 5-A Behavioral Counseling Framework topic in the Direct Services Section of this document.
	<sup>3</sup> WISEWOMAN Direct Services Cost Worksheet can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The worksheet can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.

#### 60/40 Distribution of Cooperative Agreement Funds\*

#### 60% of Funds

#### **Participant Recruitment**

Activities to recruit individual BCCEDP participants into WISEWOMAN

#### **Screening and Diagnostic Services**

Reimbursement of health care provider time or fees for the WISEWOMAN portion of baseline screening and rescreening office visits and diagnostic office visits

Lab costs for screening and diagnostic tests

#### **Case Management of Alerts**

Coordinating timely and appropriate medical care for women with alert screening values

#### **Risk Reduction Counseling**

Time spent verbally reviewing results of baseline screening and rescreening when results are not available at the time of the office visit and risk reduction counseling cannot occur as part of the office visit

#### **Lifestyle Intervention (LSI)**

Time spent delivering individualized diet and physical activity LSIs to participants

Coordinating women's participation in LSIs

Purchasing materials/items to be provided to individual participants as part of the LSI or to support maintenance of heart healthy behaviors (e.g., cookbooks, pedometers)

#### **Support Services**

Time spent contacting a participant to ensure that she completes the LSI

Transportation for participants

Individual translation services

Incentives used to recruit a woman into the program, help a woman adopt and maintain behavior change, or complete program direct services

#### Other

Printing forms and materials to be distributed to individual participants

Mailing materials to individual participants

#### 40% of Funds

#### **Program Management**

Management and planning

Administrative costs and personnel

Curriculum and materials development

Web site development and maintenance

Reporting requirements such as continuation application, interim progress report, annual progress report, and semi-annual submission of minimum data elements and cost data

#### Billing

Media campaigns and other activities that increase awareness of the WISEWOMAN program

Professional development (to include conferences and trainings)

Development of newsletters or updates for providers

#### **Partnerships**

Cost of travel to meet with partners

Provision of resources for development of heart healthy community initiatives where WISEWOMAN participants live

Educating the public about heart disease and stroke prevention

#### **Evaluation**

Entering, tracking, and monitoring data (at both the individual and aggregate levels)

Evaluation of activities to identify

opportunities for planning and improvement

Audits to determine quality of care

Focus groups or surveys with providers or participants

Cost effectiveness assessments

Documentation and dissemination of evaluation findings

<sup>\*</sup> Does not apply to non-Federal matching funds.

## **Legislative Requirements**

Requirements	State/Tribal programs must follow the legislative requirements detailed in 42 U.S.C. Section 300k of the Public Health Service Act, as amended. NBCCEDP funded programs also follow these requirements.
Guidance	WISEWOMAN was originally authorized as a demonstration project in 1993 through a legislative supplement to The Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). This law and later amendments specify the required functions of all WISEWOMAN programs as:  Providing preventive health services that include blood pressure, cholesterol, and health education (i.e., provide heart disease and stroke risk factor screening and lifestyle interventions) to women receiving services through NBCCEDP.  Providing appropriate referrals for medical treatment.  Improving the education, training, and skills of health professionals.  Developing and disseminating public information and education programs.  Monitoring the quality and interpretation of screening procedures.  Evaluating the above activities.
	<ul> <li>The legislation also requires that WISEWOMAN programs:</li> <li>Match funds from non-Federal sources in an amount not less than one dollar for every three dollars of Federal funds awarded.</li> <li>Use for match only the amount of non-Federal contributions in excess of the average amount made by the State for the 2-year period preceding the first fiscal year for which the State applied and received funding (this is referred to as Maintenance of Effort).</li> <li>Be the payer of last resort. (This means that funded programs cannot use WISEWOMAN funds to pay for any services that are covered by a State compensation program, an insurance policy, a Federal or State health benefits program, or an entity that provides health services on a prepaid basis.) Exception: Indian Health Services (IHS) is the payer of last resort if these funds are available.</li> <li>Use at least 60% of funds on direct services (e.g., screening, risk reduction counseling, lifestyle intervention(s), diagnostic exams, case management for women with alert values, support services used to maximize participation in screening and lifestyle intervention services).</li> <li>Spend no more than 10% of Federal funds annually for administrative expenses.</li> <li>Do not use grant funds for inpatient hospital services (nor does the WISEWOMAN Program allow funds to be spent on treatment or medication).</li> </ul>

	<ul> <li>Limit the imposition of fees for services on participants.</li> <li>Provide services through entities that provide breast and cervical cancer screening.</li> <li>Provide assurances that the grant funds will be used in the most cost-effective manner.</li> <li>Most, if not all, of the requirements listed above are discussed throughout this document.</li> </ul>
Monitoring	CDC staff members will review minimum data elements, the budget and budget narrative, policies and procedures, training records, and other data sources to determine if the State/Tribal program is following the legislative requirements.
References	<sup>1</sup> Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the amendment that led to the creation of WISEWOMAN can be found at <a href="http://www.cdc.gov/wisewoman/legislation_highlight.htm">http://www.cdc.gov/wisewoman/legislation_highlight.htm</a>

## **Matching Funds**

Requirements	In accordance with Public Law 101-354 and its amendments <sup>1</sup> State/Tribal programs are required to match funds from non-Federal sources in an amount not less than one dollar for every three dollars of Federal funds. Matching funds must be tied to services or activities that directly benefit the WISEWOMAN program.
	The amount and the source used to satisfy the matching requirement must be documented by the program and are subject to audits.
Guidance	Generally, if Federal funds are allowed for a service or activity, then non-Federal contributions for the same service or activity may be allowed as a source of matching funds. For example, if a funded program uses State/Tribal Organization funds to support WISEWOMAN services or activities, the amount of State/Tribal Organization funding used can be counted towards the matching requirement.
	If the funded program is a Tribal Organization, Public Law 93-638 authorizes the use of funds received under the Indian Self-Determination and Education Assistance Act as matching funds. <sup>2</sup>
	<ul> <li>Matching funds may be cash, in-kind, or donated services contributed by the funded program and its partners (including for-profit entities). Ideas for match include, but are not limited to:         <ul> <li>Work with partners, such as American Heart Association, American Lung Association, Department of State Parks and Recreation, and State universities to donate incentives (e.g., pedometers, cookbooks), donate materials or literature on heart health, cover the cost of mailings, donate staff time, and provide professional education to help meet the goals of WISEWOMAN.</li> <li>Work with media outlets to donate media time for public education, awareness, and to promote WISEWOMAN.</li> <li>Use the difference between the usual and customary fees for screening services and what Medicare, Part B allows.</li> <li>Require that local service providers contribute to the match requirement.</li> </ul> </li> </ul>
	<ul> <li>If uncompensated, use the time providers/staff/volunteers spend in WISEWOMAN trainings and advisory meetings.</li> </ul>
	Matching funds may <u>not</u> include:  1. Payment for treatment services or the donation of treatment services.  2. Services assisted or subsidized by the Federal government.  3. The indirect or overhead costs of an organization.

	Specific rules and regulations governing the matching fund requirement are included in the PHS Grants Policy Statement, Section 6. <sup>3</sup> Matching funds are not subject to the 60/40 requirement.
Monitoring	CDC staff members will review the amount and source of matching funds submitted to determine if the State/Tribal program is meeting non-Federal match requirements.
References	<sup>1</sup> Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the amendment that led to the creation of WISEWOMAN can be found at <a href="http://www.cdc.gov/wisewoman/legislation_highlight.htm">http://www.cdc.gov/wisewoman/legislation_highlight.htm</a> . <sup>2</sup> Indian Self-Determination and Education Assistance Act, Public Law 93-638 can be found at <a href="http://www.oiephr.bia.edu/Adobe/Training%20Handouts/Public%20Law%2093-638.pdf">http://www.oiephr.bia.edu/Adobe/Training%20Handouts/Public%20Law%2093-638.pdf</a> .
	The PHS Grants Policy Statement, Section 6 can be found at <a href="http://grants.nih.gov/grants/policy/gps/6sources.htm">http://grants.nih.gov/grants/policy/gps/6sources.htm</a> .

## **Materials Development**

Requirements	CDC retains an unrestricted right to use, reproduce, adapt, and disseminate for its own purposes, products that may be developed using WISEWOMAN Federal funds by WISEWOMAN cooperative agreement recipients, contractors, subcontractors, vendors, or consultants. These products may include, but are not limited to, the following: program curriculum, program participant materials, graphic designs, educational and other informational materials, fact sheets, newsletter templates, and manuals. [See DHHS grants regulation at 45CFR Section 74.36] <sup>1</sup>
Guidance	State/Tribal programs working with contractors or consultants to develop materials for their WISEWOMAN program will want to make sure that the contractor/consultant is aware of this requirement. It is suggested that programs provide the requirement in writing to any entity involved in materials development.
	It is appropriate for funded programs to note the funding source on any material or publication developed using WISEWOMAN funds. An appropriate citation would be:
	The creation of this XYZ was made possible by cooperative agreement DP08-804 from the Centers for Disease Control and Prevention/Division for Heart Disease and Stroke Prevention/WISEWOMAN Program.
	To increase name recognition and awareness of the WISEWOMAN Program, funded programs are encouraged to use the name WISEWOMAN (all capital letters, as it is an acronym) whenever possible on written materials.
Monitoring	CDC staff members will review materials and publications generated by the State/Tribal program to determine if the program is following the materials development requirements.
References	<sup>1</sup> The Code of Federal Regulations, Title 45. See Part 74 (Uniform Administration Requirements), Part 92 (Uniform Administration Requirements, State and Local Governments), and Part 93 (New Restrictions on Lobbying) can be found at <a href="http://www.hhs.gov/foia/45cfr5.html">http://www.hhs.gov/foia/45cfr5.html</a> .

## **National Clinical Care, Diet, and Lifestyle Recommendations**

Requirements	To ensure that participants receive high-quality care, State/Tribal programs should contract only with health care practitioners and lifestyle interventionists who agree to provide care and interventions in accordance with the following national clinical care, diet, and physical activity recommendations. In addition, the program should offer these practitioners professional development opportunities that promote the use of national recommendations.
Guidance	National guidelines for working with participants to modify or prevent risk factors can be found on the following Web links. CDC recognizes that these are guidelines and recommendations and that a responsible practitioner's judgment remains paramount.
	<u>Clinical</u>
	Blood Pressure
	The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)
	http://www.nhlbi.nih.gov/guidelines/hypertension/
	Cholesterol National Cholesterol Education Program, Adult Treatment Panel III Report (ATP III)
	http://www.nhlbi.nih.gov/guidelines/cholesterol/
	Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines <a href="http://rover2.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm">http://rover2.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm</a>
	Overweight and Obesity
	Obesity Education Initiative's Guidelines for Weight Management <a href="http://www.nhlbi.nih.gov/about/oei/">http://www.nhlbi.nih.gov/about/oei/</a>
	The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults <a href="http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm">http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm</a>
	<u>Diabetes</u> American Diabetes Association Clinical Practice Recommendations 2008 <a href="http://care.diabetesjournals.org/content/vol31/Supplement_1/#POSITION_STATEMENTS">http://care.diabetesjournals.org/content/vol31/Supplement_1/#POSITION_STATEMENTS</a>

	<u>Diet &amp; Lifestyle</u>
	Diet Diet and Lifestyle Recommendations Revision 2006. A Scientific Statement From the American Heart Association Nutrition Committee <a href="http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.106.176158v1">http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.106.176158v1</a>
	Dietary Guidelines for Americans <a href="http://www.healthierus.gov/dietaryguidelines/">http://www.healthierus.gov/dietaryguidelines/</a>
	Therapeutic Lifestyle Changes (TLC) diet principles (ATP III) <a href="http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm">http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm</a>
	DASH eating plan (JNC 7) <a href="http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/">http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/</a>
	Physical Activity CDC/American College of Sports Medicine (ACSM) recommendations <a href="http://www.cdc.gov/nccdphp/dnpa/physical/recommendations/older adults.htm">http://www.cdc.gov/nccdphp/dnpa/physical/recommendations/older adults.htm</a>
	Surgeon General's recommendations for physical activity <a href="http://www.cdc.gov/nccdphp/sgr/contents.htm">http://www.cdc.gov/nccdphp/sgr/contents.htm</a>
	The Task Force on Community Preventive Services systematic reviews of community interventions to increase physical activity <a href="http://www.thecommunityguide.org/pa/default.htm">http://www.thecommunityguide.org/pa/default.htm</a>
	Tobacco Use U.S. Department of Health and Human Services Clinical Practice Guideline: Treating Tobacco Use and Dependence <a href="http://www.surgeongeneral.gov/tobacco/default.htm">http://www.surgeongeneral.gov/tobacco/default.htm</a>
Monitoring	CDC staff members will review policies and procedures, training records, contracts/memorandums of understanding, and other data sources to determine if the State/Tribal program is working with providers that agree to follow national clinical care, diet, and lifestyle recommendations.

## Official Correspondence with CDC

Requirements	Each year State/Tribal programs must provide CDC with documentation that includes, but is not limited to, an interim progress report, annual progress report, and financial status report. These documents should be submitted to CDC via <a href="www.grants.gov">www.grants.gov</a> or sent to a designated grants management specialist who works in the Procurements and Grants Office (PGO).
Guidance	Requests to PGO Funded programs should do the following to increase the likelihood of having requests approved by the grants management specialist at PGO:  Review request with WISEWOMAN project officer before submitting it to PGO.  Provide a courtesy copy to project officer of all correspondence with PGO. This can be an electronic or hard copy.  Include in all correspondence to PGO the following items:  A cover letter with two signatures (the signature of the principal investigator and the signature of the business office official).  The grant number. This number is found on the Notice of Award.  If it includes a budgetary request for a contractor, include the following:  Name of Contractor  Method of Selection  Period of Performance  Scope of Work  Method of Accountability  Itemized budget with justification for each line item  If it includes a budgetary request with match information, include the following:  Source of match  Amount of match  Method of establishing value of noncash match  Method of documenting actual match received  If the information listed above is not available, the funded program should indicate "To Be Determined" until the information becomes available. As soon as it is available, it should then be submitted to the grants management specialist.

#### **Reports and Other Documents**

- Interim Progress Report: The interim progress report is due February 15 and must be submitted to CDC via <a href="www.grants.gov">www.grants.gov</a>. The progress report serves as the non-competing continuation application and must contain the following elements:
  - 1. Standard Form ("SF") 424S
  - 2. SF-424A, Budget Information-Non-Construction Programs
  - 3. Budget Narrative
  - 4. Indirect Cost Rate Agreement if applicant is requesting indirect costs in the budget
  - 5. Program Narrative
  - 6. Annual work plan for the next budget year
  - 7. List of current procedural terminology (CPT) codes that are used for reimbursement of direct services

The interim progress report should also include a succinct description of the funded program's accomplishments and progress made in meeting each of the current budget period activities and objectives during the first 6 months of the budget period (June 30 through December 31). If objectives are not met, the funded program should provide the reason(s) for not meeting them and identify strategies to be implemented to achieve unmet objectives.

Note: It is suggested that funded programs use the WISEWOMAN Direct Services Cost Worksheet<sup>1</sup> to develop the Budget and Budget Narrative.

- Annual Progress Report: Funded programs must provide CDC with an original plus two hard copies of the annual progress report by September 30 of each budget year. The progress report should include a description of the funded program's accomplishments and progress made for the 12-month budget period (June 30 through June 29).
- Financial Status Report (FSR): Funded programs must provide CDC with an original plus two hard copies of the FSR, which is used to officially report any unobligated funds to CDC. An FSR is required for each budget period and the final project period. Ninety days after the end of each budget period, an FSR is due to PGO (by September 30). However, funded programs may make adjustments up to 15 months after the end of the budget period. The funded program should submit documentation of its current year's estimated unobligated dollars on the SF 424A (Standard Form 424A, Budget Information Non-Construction Programs), which is submitted with the continuation application.

	<ul> <li>Final Performance Report and FSR: Funded programs must provide CDC with an original plus two hard copies of the Final Performance Report and FSR. These reports are due by September 30, 2013.</li> <li>Prior Approval Requirements: Once funds have been awarded, funded programs must obtain written prior approval from PGO for the changes listed below. Failure to obtain prior approval might result in the disallowance of funds. The following changes are some of the more common or relevant items that need prior approval<sup>2</sup>:         <ol> <li>Change in program manager/director, principal investigator or other key staff or the absence thereof for more than 3 months.</li> <li>Change in program scope or objectives, regardless of whether the budget is affected.</li> <li>Transferring substantive programmatic work by contracting or any other means to a third party.</li> </ol> </li> </ul>
	<ol> <li>Carryover of unobligated funds from one budget period to another within an approved project period.</li> <li>Extensions of the budget/project period with or without additional funds.</li> <li>Re-budgeting or redirecting a cumulative amount of funds for the current budget period that exceeds 25% of the total amount awarded, or \$250,000, whichever is less.</li> <li>Redirection of funds that were intended for training costs.</li> <li>Publication and printing costs exceeding \$25,000 for a single publication when not included in the originally approved budget.</li> <li>Requests for additional Federal funds.</li> </ol>
Monitoring	CDC staff members will communicate with the State/Tribal program and PGO to determine if all required reports are submitted
References	<sup>1</sup> The WISEWOMAN Direct Services Cost Worksheet can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The document can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum. <sup>2</sup> This information was presented during a CDC Project Officer of the Future course entitled <i>Navigating Cooperative Agreements with Our Partners to Achieve Public Health Results</i> on February 2, 2005.

## **Professional Development**

Requirements	State/Tribal programs must provide on-going training that includes information on early detection and prevention of heart disease and stroke and CDC WISEWOMAN Program requirements for all staff members/contractors who deliver WISEWOMAN direct services.
Guidance	State/Tribal programs need to identify training needs for all staff members/contractors who deliver WISEWOMAN direct services.  In addition to the required trainings on early detection and prevention of heart disease and stroke and CDC WISEWOMAN Program requirements, the following training topics are important for staff members who provide direct services to participants:  National clinical care, diet, and lifestyle recommendations Accurate blood pressure measurements The 5-A Behavioral Counseling Framework Women and heart disease Behavior change strategies Communicating with participants in easy-to-understand language Cultural Competence How to identify appropriate community-based resources and link women to them
Monitoring	CDC staff members will review the work plan, training records (including agenda, learning objectives, and list of attendees), and other data sources to determine if the State/Tribal program provides trainings in accordance with CDC WISEWOMAN Program requirements.

## **Staffing**

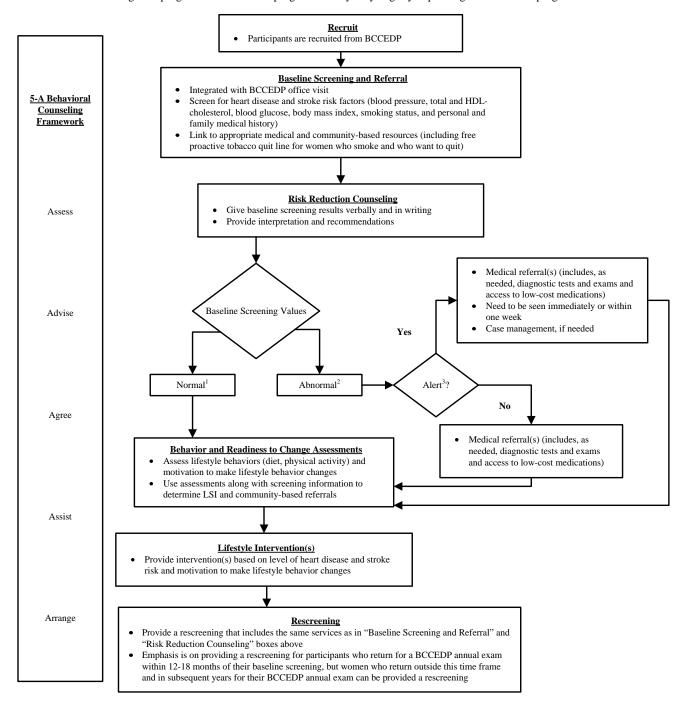
C	
Requirements	<ul> <li>State/Tribal WISEWOMAN programs must:</li> <li>Employ one full-time program manager (one person devoting 100% time to this cooperative agreement). This person will oversee the administration of all WISEWOMAN activities, including fiscal management, program services, and evaluation.</li> <li>Identify staff members who will be responsible for overseeing the lifestyle intervention; data collection and reporting; fiscal management; and quality improvement and evaluation activities of the program.</li> <li>Ensure that State/Tribal staff members have the relevant background, qualifications, and experience necessary to implement all CDC WISEWOMAN Program requirements.</li> </ul>
Guidance	State/Tribal programs are encouraged to employ staff with experience in nutrition, physical activity, health education, or behavior change to oversee all lifestyle intervention activities, ensure the lifestyle intervention(s) are implemented as intended, provide written justification for any changes in the lifestyle intervention(s), and ensure evaluation of lifestyle intervention activities.  The staff member who will manage WISEWOMAN data will need to develop, implement, and maintain a system to collect all Minimum Data
	Elements (MDEs) and similar evaluation data; be responsible for the submission of accurate and timely MDE/evaluation data; and work with the State/Tribal BCCEDP to reduce redundancy in data collection of both programs and capitalize on existing BCCEDP data systems.
	Programs may want to consider sharing staff with BCCEDP and other chronic disease prevention programs as a cost saving strategy. For example, the data manager may work for both BCCEDP and WISEWOMAN and the evaluator may work for WISEWOMAN and the State/Tribal chronic disease section. The CDC WISEWOMAN Program supports the use of sharing relevant staff because of the crosscutting nature of the Program. However, because of the complexities of WISEWOMAN, funded programs must meet the minimum staffing requirements as noted above.
	Programs that have difficulty hiring staff must develop a plan to contract out or identify alternative methods for meeting the staffing requirements. During the interim period, before the required staff has been hired, the staffing plan should indicate who will complete each of the major responsibilities listed above.

Monitoring	CDC staff members will review the staffing plan, resumes/curriculum vitae, position descriptions, and other data sources to determine if the State/Tribal
	program has appropriate staffing.

# Section 2 Direct Services

#### Flow Diagram for WISEWOMAN Direct Services

The diagram below presents the typical progression of how participants enter into the WISEWOMAN program and flow through the program services. This progression may vary slightly depending on the funded program structure.



<sup>&</sup>lt;sup>1</sup>Normal Screening Values: <120 mmHg Systolic Blood Pressure (BP) and <80 mmHg Diastolic BP; <200 mg/dL Total Cholesterol; ≥40 mg/dL HDL Cholesterol; <100 mg/dL LDL Cholesterol; <150 mg/dL Triglycerides; <200 mg/dl Non-fasting Blood Glucose (BG) with no symptoms; <100 mg/dl Fasting BG; <140 mg/dl Oral Glucose Tolerance Test (OGTT)

<sup>&</sup>lt;sup>2</sup>Abnormal Screening Values: ≥120 mmHg Systolic BP or ≥80 mmHg Diastolic BP; ≥200 mg/dL Total Cholesterol; <40 mg/dL HDL Cholesterol; ≥100 mg/dL LDL Cholesterol; ≥150 mg/dL Triglycerides; ≥200 mg/dl Non-fasting BG plus symptoms; ≥100 mg/dl Fasting BG; ≥140 mg/dl OGTT <sup>3</sup>Alert Screening Values: >180 mmHg Systolic BP or >110 mmHg Diastolic BP; >400 mg/dL Total Cholesterol; >375 mg/dl Non-fasting BG; >375 mg/dl Fasting BG

## **5-A Behavioral Counseling Framework**

Requirements	State/Tribal programs must have systems in place to ensure that all 5 A's of the 5-A Behavioral Counseling Framework (Assess, Advise, Agree, Assist, Arrange) are delivered to all participants.
Guidance	The report, <i>Counseling to Promote a Healthy Diet</i> , 1 created for the Agency for Healthcare Research and Quality (AHRQ), found the 5-A Behavioral Counseling Framework to be useful in describing how interventions that combine nutrition education with behavior-oriented counseling affect change. The CDC WISEWOMAN Program has adopted the use of the 5-A Behavioral Counseling Framework to describe how the Program's direct services affect change.
	State/Tribal programs should provide training on the 5-A Behavioral Counseling Framework for all WISEWOMAN screening and lifestyle intervention providers.
	As part of the planning process to implement WISEWOMAN, State/Tribal programs need to identify how, when, and by whom the 5 A's will be delivered to all participants.
	Examples of activities for each of the 5 A's include, but are not limited to:
	<u>Assess</u> : Assess heart disease and stroke risk factors, lifestyle behaviors, and readiness to make lifestyle behavior changes (and progress made towards achieving goals).
	<u>Advise</u> : Provide advice based on risk status through risk reduction counseling, discuss medication use and adherence (if applicable), and emphasize the benefits of behavior change.
	<u>Agree</u> : Obtain agreements through collaborative goal setting for lifestyle behaviors and if needed, medical care.
	Assist: Provide assistance by helping identify strategies for overcoming barriers to developing, changing, or maintaining health behaviors; assisting with development of the skills and confidence necessary to successfully develop, change, or maintain health behaviors; and helping to increase social/environmental supports.
	<u>Arrange</u> : Help arrange follow-up appointments (e.g., lifestyle intervention sessions, medical appointments) and when appropriate, link to low-cost medical or community-based resources to support heart health.

Below is an example of a flow diagram from the World Health Organization that shows how the 5 A's can be used to facilitate and support behavior change and self-management of chronic conditions. State/Tribal programs might find this example useful when developing their flow diagram that shows how all WISEWOMAN participants will receive all 5 A's of the 5-A Behavioral Counseling Framework. TWO PATHS TO 5 As DELIVERY 5 A action **Timing Sequence of Activities** ASSESS Mail-out, telephone, Internet or **Before Visit** (Staff/ Waiting Room Assessment & Feedback Reception) **ADVISE** Discuss Risk Factors in Personal. Before or Meaningful Way, and Advise Behavior Change (Physician) **During Visit AGREE** Agree on Specific, Collaboratively **During Visit** (Physician, Set Goals and Priorities Nurse, or IT) **ASSIST Identify Barriers to** Refer to Group or (Nurse, Goals, <u>Assist</u> with Problem-solving Individual Evidence-Educator, **During or** Technology, **Based Counseling** After Visit Program, Community Resources Strategies and **Health System** Action Plan or Community Program) **ARRANGE** Follow-up Reinforcement, (Automated, Monitoring, Link information **After Visit** phone call, eback to all staff mail, etc.) © World Health Organization 2004 **Monitoring** CDC staff members will use data and information from site visits, policies and procedures, flow diagrams, case studies, and other data sources to determine if the State/Tribal program is delivering all 5 A's of the 5-A Behavioral Counseling Framework to all participants. <sup>1</sup> The report, Counseling to Promote a Healthy Diet, can be found at References www.ahrq.gov/downloads/pub/prevent/pdfser/dietser.pdf.

### **Alert Values and Case Management**

#### **Requirements**

For all women with any alert screening value (estimated to be 1% of all women screened), State/Tribal programs must:

- Verify that they are evaluated and treated immediately or within 1 week, depending on the clinical situation and complications, in accordance with national and Program guidelines.
- Identify solutions to overcome barriers to make it possible for them to receive medical care in accordance with national and Program guidelines.
- Submit to CDC documentation of services received and include a written explanation for any woman with an alert value who does not receive medical care and/or medication.

Minimum data elements<sup>1</sup> related to women with alert values must be collected and submitted to CDC.

#### Guidance

The National Health and Nutrition Examination Survey (NHANES) and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) were used to identify alert values for the WISEWOMAN Program. The alert screening values are:

- Systolic blood pressure >180 mmHg
- Diastolic blood pressure >110 mmHg
- Fasting or non-fasting total blood cholesterol >400 mg/dL
- Fasting or non-fasting blood glucose >375 mg/dl

Case management is an intensive support service used to ensure that women with alert screening values receive appropriate and timely medical care. Case management involves strategies that reduce barriers to women understanding the treatment regimen, receiving medication, and attending medical appointments.

If women with alert screening values are not receiving care in accordance with national and Program guidelines, State/Tribal programs should conduct a special study or audit to determine if referral procedures or provision of care needs improvement.

Case management services may be reimbursed for women who have alert screening values. WISEWOMAN-funded case management services must end when a woman with alert values begins receiving prescribed treatment or is no longer eligible for WISEWOMAN (e.g., no longer eligible for NBCCEDP). For women with alert values who are no longer eligible for WISEWOMAN, it is important to ensure they are directed to a health care professional who will see them regardless of their financial status or other

	circumstances before case management services are stopped.  The WISEWOMAN Best Practices Toolkit <sup>2</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for case management of women with alert values.  Note: Due to limited resources, WISEWOMAN funds cannot be used for case management of women with non-alert clinical values.
Monitoring	CDC staff members will review minimum data elements and other data sources to determine if the State/Tribal program has systems in place that result in timely and appropriate medical follow-up of participants with alert values.
References	<sup>1</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum. <sup>2</sup> The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a> . The Toolkit can be found in the Publications section on the Web page.

## **Baseline Screenings**

Requirements	The following must be assessed at the baseline screening for all WISEWOMAN participants. (Note: The WISEWOMAN baseline screening is to take place as part of the BCCEDP annual exam office visit.)
	screening is to take place as part of the Beelbi annual exam office visit.)
	Blood pressure (must record two systolic and two diastolic measurements)
	2) Fasting or non-fasting total and HDL cholesterol, at minimum (If participants are fasting, a lipoprotein panel may be used, which includes LDL cholesterol and triglycerides)
	3) Fasting or non-fasting blood glucose, except for women previously diagnosed with diabetes it is recommended by the American Diabetes Association <sup>1</sup> that they receive an A1C (glycated hemoglobin) test for the purposes of monitoring blood glucose control
	<ul><li>4) Body mass index (using measured height and weight)</li><li>5) Smoking behavior</li></ul>
	6) Personal history of high cholesterol, high blood pressure, diabetes, and medications for these conditions
	7) Personal history of heart attack, angina, coronary heart disease, or stroke
	8) Brief family history of stroke, heart attack, and diabetes
	All clinical policies and procedures must follow national clinical care guidelines and be approved by individuals with appropriate medical qualifications at the State/Tribal level.
	All baseline screening measures must be completed in a timely manner and must be completed before a woman can participate in the lifestyle intervention since the screening results are used to help determine to which lifestyle intervention and/or community-based resources she will be referred.
	Minimum data elements <sup>2</sup> related to baseline screening measures must be collected and submitted to CDC.
Guidance	State/Tribal programs should work with individuals who have expertise in heart disease and stroke prevention to determine what the program should expect from screening providers to ensure that screening and referral services are provided in accordance with national clinical care recommendations and CDC WISEWOMAN Program requirements.

Programs need to develop a method to collect and report the information listed in items 1-8 in a standardized format established by CDC. The format is specified in the WISEWOMAN Data User's Manual.<sup>2</sup>

Accurate blood pressure measurements are critical for detecting and managing high blood pressure. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) report<sup>3</sup> recommends the following for accurately measuring blood pressure:

- Participants should not smoke, exercise, or have caffeine for at least 30 minutes before their blood pressure is measured.
- Participants should be seated quietly for at least 5 minutes in a chair (rather than on an exam table), with feet on the floor and arms supported at heart level.
- To ensure accuracy, an appropriate sized cuff should be used (cuff bladder encircling at least 80% of the arm).
- Use a mercury sphygmomanometer, a recently calibrated aneroid manometer, or a validated electronic device to measure blood pressure.
- Systolic blood pressure is the point at which the first of two or more sounds is heard (phase 1), and diastolic blood pressure is the point before the disappearance of sounds (phase 5).
- At least two measurements should be taken and recorded, separated by a minimum of 2 minutes. If the first two readings differ by more than 5mmHg, additional measurements should be taken. (This information does not appear in JNC 7 but is specified in JNC 6).
- Each participant should be given specific blood pressure numbers and goals, both verbally and in writing.

National clinical screening guidelines recommend a complete fasting lipid panel to assess for hypercholesterolemia and fasting blood glucose to assess for diabetes. While CDC also prefers this type of testing, it is recognized that some of the participants are likely to have not fasted since WISEWOMAN baseline screenings are to occur during the BCCEDP screening visit. Therefore, programs are allowed to submit values for total cholesterol and HDL cholesterol using non-fasting methods. If LDL cholesterol and triglycerides are measured at the baseline screening appointment, they should be done using fasting methods. For women not previously diagnosed with diabetes, programs can submit values for glucose using non-fasting methods.

Programs need to develop a process to ensure that women who are previously diagnosed with diabetes receive an A1C test instead of a glucose test.

The following recommendations regarding fasting status should be followed: • The American Heart Association recommends that a person fast for 9-12 hours before a fasting lipid panel is done. • The American Diabetes Association<sup>1</sup> recommends that a person fast for 8-10 hours before a fasting blood glucose test is done. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults<sup>5</sup> recommends that for women found to have a body mass index (BMI) between 25 and 34.9 kg/m<sup>2</sup>, the health care provider should also measure waist circumference. A high waist circumference (>35 inches for women) is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and cardiovascular disease. Programs should use the results of the baseline screening (items 1-8 listed in the requirements section of this topic) and assessments related to diet, physical activity, and readiness to make lifestyle behavior changes to match each participant with the appropriate lifestyle intervention and/or community-based resources. CDC staff members will review reports generated using data collected at **Monitoring** the baseline screening visit and other data sources to: 1) determine if the State/Tribal program is meeting requirements related to baseline screenings: 2) determine if the program has met its screening projection; 3) determine the data quality; and 4) describe the prevalence of risk factors in the State/Tribal population served. CDC staff members will review the State/Tribal program work plan and other data sources to determine if individuals with appropriate medical qualifications are included in the process of developing and reviewing clinical policies, procedures, and quality assurance activities. <sup>1</sup> Additional information from the American Diabetes Association can be References found at www.diabetes.org. <sup>2</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a>. Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum. <sup>3</sup> Additional information on JNC 7 and JNC 6 can be found at http://www.nhlbi.nih.gov/guidelines/hypertension/.

	<sup>4</sup> Additional information from the American Heart Association can be found at <a href="https://www.americanheart.org">www.americanheart.org</a> .
	<sup>5</sup> The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults can be found at <a href="http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm">http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm</a> .
Key Related Topics	Behavior and Readiness to Change Assessments National Clinical Care, Diet, and Lifestyle Recommendations Office Visits Rescreenings

## **Behavior and Readiness to Change Assessments**

	O
Requirements	State/Tribal programs must complete assessments related to diet, physical activity, and readiness to make lifestyle behavior changes for all WISEWOMAN participants.
	Programs should use baseline screening results; behavioral goals; and assessments related to diet, physical activity, and readiness to make lifestyle behavior changes to determine the type and intensity of the lifestyle intervention a participant will be offered or if she only needs risk reduction counseling and to be linked to community-based resources.
Guidance	Assessments related to diet, physical activity, and readiness to make lifestyle behavior changes need to be approved by CDC staff members prior to implementation.
	State/Tribal programs need to determine when the behavior and readiness to change assessments are conducted with participants. Programs are encouraged to take into account the burden placed on providers when determining at what point in the process of delivering services the assessments will be done (e.g., at the screening appointment, as part of the lifestyle intervention).
	Examples of approaches that can be used to assess readiness to make lifestyle changes include, but are not limited to the transtheoretical model and the motivational interviewing approach, as they include strategies to assess motivation or readiness to make changes.
	Examples of behavioral assessments related to diet and physical activity can be found in the materials included with the translated lifestyle interventions at <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> .
	Although programs are required to assess each participant's lifestyle behaviors related to diet and physical activity and readiness to make lifestyle behavior changes, programs are not required to submit the data collected from these assessments as part of the minimum data element (MDE) file and these data are not currently covered under OMB clearance number 0920-0612. However, if State/Tribal programs wish to voluntarily submit data collected from these assessments along with their MDEs, CDC will have the capacity to accept and review this information.
	Programs that wish to submit optional data from assessments of readiness to make lifestyle changes and lifestyle behaviors related to diet and physical activity will be required to use CDC's standardized questions for these

assessments. These questions will be developed at a later date. Programs

	will be required to use the exact wording, response options, and response format for the questions and follow the reporting requirements that are outlined in the WISEWOMAN Data User's Manual. <sup>3</sup> The same questions must be asked as part of the assessment process and after the lifestyle intervention/at the end of program participation. The assessment questions will be set up as a block of questions. If the State/Tribal program wants to ask additional questions related to diet and physical activity and readiness to make lifestyle changes, those questions must be asked <u>after</u> the CDC block of questions is presented to the participant.
	While the data from assessments related to readiness to make lifestyle changes and lifestyle behaviors related to diet and physical activity are not required as part of the MDE file, programs are strongly encouraged to use the recommended questions as part of their assessments once the questions are developed and made available by the CDC WISEWOMAN Program. The list of recommended questions will evolve over time as more data and evidence becomes available.
Monitoring	CDC staff members will review data collection forms, flow diagram, policies and procedures, and other data sources to determine if behavior and readiness to change assessments are done for each participant.
References	<sup>1</sup> Additional information about the Transtheoretical Model can be found at <a href="http://www.uri.edu/research/cprc/TTM/detailedoverview.htm">http://www.uri.edu/research/cprc/TTM/detailedoverview.htm</a> . <sup>2</sup> Additional information about Motivational Interviewing can be found at <a href="http://www.motivationalinterview.org/">http://www.motivationalinterview.org/</a> . <sup>3</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.

# Community-based Referrals and Resources for Heart Healthy Behaviors

Requirements	To help WISE
	behaviors, Star

To help WISEWOMAN participants develop and maintain heart healthy behaviors, State/Tribal programs must work with screening and lifestyle intervention providers who 1) are knowledgeable about affordable and accessible resources in the communities where WISEWOMAN participants live, work, and play and 2) have a way to link women to these resources.

If the communities lack affordable heart healthy resources, State/Tribal programs must work with providers and relevant public health experts and organizations to promote the development of heart healthy resources and environments.

Minimum data elements<sup>1</sup> related to linking participants to community-based nutrition, physical activity, and tobacco cessation resources must be collected and submitted to CDC.

#### Guidance

This guidance document refers to two types of community-based resources:

- 1) Evidence-informed lifestyle interventions for which WISEWOMAN funds are used.
- 2) Resources that are free or low-cost for which little or no WISEWOMAN funds are used.

To ensure the most efficient use of WISEWOMAN funds, State/Tribal programs will need to identify and link women to free or low-cost community-based resources. The guidance included for this topic (Community-based Referrals and Resources for Heart Healthy Behaviors) relates to these types of resources (i.e., resources not supported with WISEWOMAN funds). For more information on WISEWOMAN-funded lifestyle interventions go to the Lifestyle Interventions topic in this Section.

Each woman should be linked with community-based resources based on her level of heart disease and stroke risk and motivation to make lifestyle changes.

Programs are strongly encouraged to partner with community organizations or businesses that will donate services or items at low or no cost to WISEWOMAN participants or the program (e.g., affordable memberships at fitness centers, reduced cost of fresh fruits and vegetables at local markets, pedometers).

	As an incentive to help women adopt heart healthy behaviors and sustain behavior change, WISEWOMAN funds can be used to purchase items to support these behaviors or offset the cost of accessing heart healthy community-based resources for a limited time. Examples include, but are not limited to, passes to access parks and recreation sites, entry fees for community walk/run events, and coupons to purchase fruits and vegetables at local markets.  Programs can find strategies for identifying barriers and promoters for heart-healthy and stroke-free living in local environments in <i>Heart Healthy and Stroke Free: A Social Environment Handbook</i> . <sup>2</sup> The WISEWOMAN Best Practices Toolkit <sup>3</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures related to community-based resources.
Monitoring	CDC staff members will review minimum data elements; speak with State/Tribal program staff during site visits; and review work plans, documentation of community-based resources, progress reports, and other data sources to determine if the State/Tribal program is working with providers that are familiar with community-based resources that support heart health and can link participants to them. If community-based resources are not available, CDC staff members will review the work plan to identify what steps are being taken to partner with others who will develop heart healthy resources and environments.
References	<ul> <li>Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a>. Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.</li> <li>Barnett E, Anderson T, Blosnich J, Menard J, Halverson J, Casper M. Heart Healthy and Stroke Free: A Social Environment Handbook, Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2007 can be found at <a href="http://www.cdc.gov/dhdsp/library/seh handbook/index.htm">http://www.cdc.gov/dhdsp/library/seh handbook/index.htm</a>.</li> <li>The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a>. The Toolkit can be found in the Publications section on the Web page.</li> </ul>
Key Related Topics	Lifestyle Interventions Minimum Data Elements

## **Consent to Participate in the Program**

Requirements		st have a process in place to obtain consent from in the WISEWOMAN Program.
Guidance	Cancer Early Detection Profession forms to reduce burden or The following table includes that determined should be	ould consider combining the Breast and Cervical rogram (BCCEDP) and WISEWOMAN consent in participants.  des items that the CDC WISEWOMAN Program included on the WISEWOMAN consent form the of the items might be worded on the forms.
	Item to Include	Examples from the Field
	Purpose and Procedures of Program	I agree to be in the (name of) program. This program has been designed to help women reduce their risk for heart disease, stroke, and other chronic diseases. This program provides <b>free</b> screening tests and a coach who will contact me to talk about easy ways to eat smart, be fit, and live well.
	List of Screening Tests	I agree to have my height, weight, blood pressure, cholesterol, and glucose measured/tested. In addition, I understand that I will be asked some personal and family medical history and health behavior questions.
	Side Effects/Discomfort of Lab Tests	The screening tests and possible side effects or discomfort have been explained to me.
	Return for Rescreening	I understand that I will be asked to participate in WISEWOMAN when I return in 12-18 months for my breast and cervical annual exam appointment. The same screening tests and paperwork will be completed at that appointment. It is very important that I return for this appointment because I will learn if there are any changes in my heart disease and stroke risk and will help (name of) program learn if this program was useful.

	Item to Include	Examples from the Field
	Obligation to Refer Women with Abnormal Screening Results	The (name of) program is required to refer you to a health care provider for medical follow up if your screening values are not normal.
	Physical Activity Clearance <sup>1</sup>	Physical activity clearance may be needed from a health care provider before you will be referred to participate in physical activity.
	Dropping out of Program	I may drop out of this program at any time.
	Confidentiality Statement	I understand that any information about me obtained as a result of my participation in program will be kept as confidential as legally possible.
	Contact information for Questions	For more information about this program, I can contact Ms. XYZ at 555-555-5555.
	<ul> <li>includes, but is not limited</li> <li>Eligibility Criteria</li> <li>Billing Responsibility</li> <li>A statement about state provider, the statement about statement a</li></ul>	
Monitoring	CDC staff members will review the consent form to determine if the State/Tribal program is using a consent form that meets all CDC WISEWOMAN Program requirements.	
References	<sup>1</sup> Programs might want to consider using the Physical Activity Readiness Questionnaire (PAR-Q) as a tool to clear women for physical activity. The tool was developed by the British Columbia Ministry of Health and an Expert Advisory Committee of the Canadian Society for Exercise Physiology revised the questionnaire in 2002. The PAR-Q can be found at <a href="http://uwfitness.uwaterloo.ca/PDF/par-q.pdf">http://uwfitness.uwaterloo.ca/PDF/par-q.pdf</a> .	

## **Current Procedural Terminology Codes**

Requirements	State/Tribal programs are only allowed to reimburse Current Procedural Terminology (CPT) codes <sup>1</sup> for screening tests, diagnostic tests, office visits, and counseling services allowed by the CDC WISEWOMAN Program.  State/Tribal programs may only reimburse at an amount no greater than what is reimbursed by Medicare, Part B. <sup>2</sup>
	Each year State/Tribal programs must submit their list of CPT codes and reimbursement rates to the CDC WISEWOMAN Program for approval along with their continuation application and budget. If changes to CPT codes are made prior to submission of the continuation application and budget, those changes must be approved by CDC.
Guidance	<ul> <li>The list below reflects the CPT codes that are most commonly used in WISEWOMAN. State/Tribal programs may choose to use these codes or to add or delete codes from this list. When developing the list of reimbursable codes remember that:</li> <li>Reimbursement for treatment services is not allowed. Treatment includes medication, medical nutrition therapy, and other highly specialized counseling such as diabetes-education programs.</li> <li>Data management fees contribute to the 40% budget category.</li> <li>State/Tribal programs must use screening, counseling, and diagnostic dollars in an efficient and appropriate manner.</li> </ul>
Monitoring	CDC staff members will review the program's list of CPT codes to determine if the State/Tribal program is only reimbursing for allowable services and procedures.
References	<sup>1</sup> Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA), consists of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. The AMA holds copyright on CPT (2001) and have registered the trademark, CPT <sup>®</sup> . <sup>2</sup> Information about Medicare Part B rates can be found at <a href="http://www.cms.hhs.gov">http://www.cms.hhs.gov</a> .
Key Related Topics	Baseline Screenings Diagnostic Tests Office Visits Rescreenings

# Allowable WISEWOMAN Primary Prevention Services and Procedures With Corresponding CPT Codes

CPT Code	Tests to Assess Cholesterol
80061	Lipid panel
80061QW	Lipid panel (CLIA waived) <sup>1</sup>
82465	Cholesterol, total
82465QW	Cholesterol, total (CLIA waived)
83718	HDL cholesterol
83718QW	HDL cholesterol (CLIA waived)
CPT Code	Tests to Assess Glucose
82947	Glucose; quantitative
82947QW	Glucose; quantitative (CLIA waived)
82948	Glucose; blood, reagent strip
82951	Glucose tolerance test, three specimens
82951QW	Glucose tolerance test, three specimens (CLIA waived)
83036	Hemoglobin, glycated (A1C) used in lieu of other glucose testing for those with previous diagnosis of diabetes
83036QW	Hemoglobin, glycated (A1C) (CLIA waived) used in lieu of other glucose testing for those with previous diagnosis of diabetes
CPT Code	Panels that include Assessment of Glucose
80048	Basic metabolic profile
80053	Comprehensive metabolic panel
CPT Code	Other
36415	Routine venipuncture
CPT Code	Office Visits (same as those allowed by NBCCEDP) <sup>‡</sup>
99201	Office visit for new patient – problem focus – 10 minutes face to face
99202	Office visit for new patient – expanded problem focus – 20 minutes face to face
99203	Office visit for new patient – low complexity – 30 minutes face to face
99211	Office visit for established patient – minimal problem – 5 minutes face to face
99212	Office visit for established patient – problem focus – 10 minutes face to face

99213	Office visit for established patient –expanded problem focus – 15 minutes face to face
99241	Consultation visit – problem focus – 15 minutes face to face
99242	Consultation visit – expanded focus – 30 minutes face to face
99243	Consultation visit – detailed focus – 40 minutes face to face
CPT Code	Preventive Medicine Evaluation Office Visits <sup>‡</sup> Preventive medicine evaluation reimbursement rates should only be used for comprehensive office visits: i.e., integrated office visits (WISEWOMAN + NBCCEDP) that include risk reduction counseling
99386	Initial preventive medicine evaluation – 40-64 Years
99387	Initial preventive medicine evaluation – 65+ Years*
99396	Periodic preventive medicine evaluation 40-64 Years
99397	Periodic preventive medicine evaluation – 65+ Years*

<sup>&</sup>lt;sup>‡</sup> It would be appropriate for State/Tribal programs to conduct a time study to determine the percent of the office visit charged against WISEWOMAN and NBCCEDP.

<sup>\*</sup> Reimbursable for Medicare Part B un-enrolled women only (e.g., women who cannot afford Medicare Part B)

Counseling Services		
If appropriate, the following CPT codes may be used for reimbursement when risk reduction counseling does not occur during the baseline screening office visit and for reimbursement of lifestyle intervention counseling.		
99401	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual, 15 minutes	
99402	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual, 30 minutes	
99403	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual, 45 minutes	
99404	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual, 60 minutes	
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting, 30 minutes	
99412	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting, 60 minutes	

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law specifies that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute. CLIA waived tests employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; pose no reasonable risk of harm to the patient if the test is performed incorrectly; and/or are cleared by the Food and Drug Administration for home use.

## **Diagnostic Tests**

Requirements	WISEWOMAN funds can only be used for the following diagnostic tests:  Fasting lipoprotein panel Fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT) Note: If a FPG or OGTT is conducted as part of the baseline screening or rescreening appointment, the results of this test should be used for diagnosis and a second fasting test should not be conducted.
Guidance	If a participant has a <b>non-fasting abnormal screening value</b> for blood cholesterol or blood glucose at the baseline screening or rescreening office visit, she should be referred for a fasting test to accurately diagnose the condition(s).  If a participant has a <b>fasting abnormal screening value</b> for blood cholesterol or blood glucose at the baseline screening or rescreening office visit, WISEWOMAN funds should <u>not</u> be used to pay for any additional diagnostic tests for the participant.  Programs are not required to submit results from diagnostic tests to CDC.
Monitoring	CDC staff members will review the program's list of CPT codes to determine if the State/Tribal program is only reimbursing for allowable diagnostic tests.
Key Related Topics	Current Procedural Terminology Codes

## **Eligibility Criteria for Participants**

Requirements	In accordance with Public Law 101-354 and its amendments, only women who are enrolled and remain eligible to participate in the State/Tribal BCCEDP are eligible to participate in WISEWOMAN.  Many of the women eligible for WISEWOMAN services represent ethnic and minority populations.  They have low incomes (250% or less of the Federal poverty guidelines).  They are underinsured or uninsured.  If they are eligible for Medicare, they are unable to pay the premium to enroll in Medicare, Part B.  WISEWOMAN places a priority on providing services to 40-64 year old NBCCEDP participants. Programs must provide rationale and receive written approval from CDC to see women younger than 40 years of age in the WISEWOMAN Program.  Minimum data elements² related to demographics must be collected and submitted to CDC.
Guidance	Programs should implement a process for recruiting BCCEDP participants into WISEWOMAN that:  Results in the highest number possible of eligible women receiving services.  Includes ethnic/minority representation similar to that of the State/Tribal BCCEDP participants.  Places a priority on serving women aged 40-64.  When considering whether to request permission to allow women younger than 40 years old to participate in WISEWOMAN, programs should determine if doing so will prevent them from meeting the NBCCEDP requirement that 75% of the women who receive mammograms must be aged 50-64.
Monitoring	CDC staff members will periodically conduct special analyses with State/Tribal WISEWOMAN and NBCCEDP data to determine if the State/Tribal program is only providing WISEWOMAN services to eligible women. Age and ethnic minority data will be analyzed in addition to NBCCEDP enrollment status.

#### References

<sup>1</sup> Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the amendment that led to the creation of WISEWOMAN are available at <a href="http://www.cdc.gov/wisewoman/legislation\_highlight.htm">http://www.cdc.gov/wisewoman/legislation\_highlight.htm</a>.

<sup>2</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a>. Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.

## **Lifestyle Interventions**

## Requirements

Lifestyle interventions (LSIs) that are supported by WISEWOMAN funds must be evidence informed (i.e., LSIs that are designed based on data relating to contributing factors, intervention strategies, or research-tested or practice-based interventions). These LSIs must:

- 1) Aim to improve diet and physical activity patterns.
- 2) Be tailored to different levels of heart disease and stroke risk and readiness to make lifestyle behavior changes.
- 3) Incorporate national diet and lifestyle recommendations.
- 4) Be culturally appropriate and delivered using easy-to-understand language.

Note: Supporting tobacco cessation efforts for women who smoke is an important aspect of LSI services. It is expected that tobacco cessation services will be provided through free proactive tobacco quit lines or other free or low-cost cessation programs rather than as part of the WISEWOMAN-funded LSI. (See the Tobacco Cessation Resources topic in the Partnerships Section of this document for more information.)

Baseline screening results; behavioral goals; and assessments related to diet, physical activity, and readiness to make lifestyle behavior changes should be used to determine the intensity of LSI a participant will be offered or if she only needs risk reduction counseling and to be linked to community-based resources.

CDC staff must review and provide written approval for the evidence base, core elements, and materials for all WISEWOMAN-funded LSIs before implementation of the LSI can occur. CDC must provide additional written approval prior to State/Tribal programs implementing changes to the originally-approved LSIs. See Appendix A for a description of the approval process.

Minimum data elements<sup>1</sup> related to the WISEWOMAN-funded lifestyle intervention must be collected and submitted to CDC.

#### Guidance

Note: When the CDC WISEWOMAN Program uses the term, *lifestyle intervention or LSI* it is referring to LSIs that address diet and physical activity and that are reimbursed using WISEWOMAN funds.

Evidence-informed lifestyle interventions have either been tested through research or evaluated in a non-research setting. Evidence-informed lifestyle interventions can be found:

 At <u>www.wiseinterventions.org</u>. Lifestyle interventions found on this Web site have been reviewed and approved for use by

- WISEWOMAN programs.
- Through a literature review for lifestyle interventions appropriate for the WISEWOMAN population and settings.
- In the community. Community-based lifestyle interventions may be used if they have been evaluated and found to be effective.

If State/Tribal programs select an LSI through a literature review or that already exists in the community, they should submit the following information about the evidence base and core elements of the LSI to CDC for review and approval prior to implementation of the LSI:

- A description of the underlying theories of the LSI.
- A step-by-step description of the evidence-based strategies of the LSI
- A summary of the results from the evidence reviewed.
- A list of the core elements, which are the elements of the LSI that are central to its theory and logic and that are thought to be responsible for its effectiveness. These core elements cannot be changed when the LSI is implemented or adapted. For an example of what will need to be submitted to CDC, go to <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> to review the approved intervention templates.

Delivery methods for the LSI may include, but are not limited to, individual counseling, group counseling, face-to-face, mail, telephone, electronic media, and/or computer.

It is not the best use of resources, nor is it practical to expect that only one version of an LSI will be able to meet the needs of women with different levels of heart disease and stroke risk and motivation to make lifestyle behavior changes. Therefore, State/Tribal programs should offer different LSIs that are matched to the participant's level of risk and motivation and implement methods to increase motivation for unmotivated high risk women.

Programs should determine how the information collected at the baseline screening and assessments related to diet, physical activity, and readiness to make lifestyle behavior changes will be used to determine if a participant only needs risk reduction counseling and to be linked to community-based resources or if LSI services are recommended.

LSIs should aim to improve diet and physical activity patterns. Women who use tobacco and are interested in quitting should be referred to the State/Tribal free proactive tobacco quit line or other free or low-cost tobacco cessation resources.

To increase the likelihood that a participant will complete the LSI (i.e., receive all core elements of the LSI to which they are referred) programs may want to:

- Implement a system to remind women to complete the LSI.
- Provide LSI services in the evening or on weekends.
- Use various methods (e.g., individual counseling, group counseling, face-to-face, mail, telephone, electronic media, computer) to deliver the LSI to reduce barriers to participation.

State/Tribal programs need to develop systems that allow them to determine if the LSI was delivered to participants as intended and identify the steps needed to ensure that women receive all core elements of the LSI to which they are referred.

To reduce heart disease and stroke risk, participants should be encouraged to aim for a desirable body weight, be physically active, avoid tobacco exposure, and follow a diet and lifestyle consistent with the following American Heart Association Diet and Lifestyle Recommendations for Cardiovascular Disease Risk Reduction (2006)<sup>2</sup>:

- Balance calorie intake and physical activity to achieve or maintain a healthy body weight.
- Consume a diet rich in vegetables and fruits.
- Choose whole-grain, high-fiber foods.
- Consume fish, especially oily fish, at least twice a week.
- Limit intake of saturated fat to <7% of energy, trans fat to <1% of energy, and cholesterol to <300 mg per day by choosing lean meats and vegetable alternatives; selecting fat-free (skim), 1%-fat, and low-fat dairy products; and minimizing intake of partially hydrogenated fats.
- Minimize intake of beverages and foods with added sugars.
- Choose and prepare foods with little or no salt.
- If consuming alcohol, do so in moderation.
- When eating foods that are prepared outside of the home, follow the AHA Diet and Lifestyle Recommendations.

The WISEWOMAN Best Practices Toolkit<sup>3</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for LSIs.

#### **Monitoring**

CDC staff members will review LSI policies and procedures, minimum data elements, monitoring systems, training records, and other data sources to determine if the State/Tribal program is implementing its LSI in accordance with CDC WISEWOMAN Program requirements and as intended.

References	<ul> <li>Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a>. Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.</li> <li>Diet and Lifestyle Recommendations Revision 2006. A Scientific Statement From the American Heart Association Nutrition Committee can be found at <a href="http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.106.176158v1">http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.106.176158v1</a>.</li> <li>The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a>. The Toolkit can be found in the Publications section on the Web page.</li> </ul>
Key Related	National Clinical Care, Diet, and Lifestyle Recommendations
Topics	Tobacco Cessation Resources

## **Medical Referrals**

Requirements	A major responsibility of State/Tribal programs is to ensure that women are referred to a health care provider for appropriate diagnostic services and medical care in accordance with national clinical care recommendations and Program guidelines. To address this, programs must ensure access to free or low-cost medical care for women who require it.	
	Minimum data elements <sup>1</sup> related to medical referrals for women with alert screening values must be collected and submitted to CDC.	
Guidance	Individual(s) with appropriate medical qualifications should assist State/Tribal programs to develop and review medical referral policies, procedures, and practices.	
	All screening providers should be trained, if needed, on how to make appropriate referrals for women who have abnormal screening values. <sup>2</sup>	
	The medical care system to which the woman is referred is responsible for providing medical follow-up and ensuring treatment. State/Tribal programs should work with providers who use a sliding fee scale to decrease the financial burden on participants.	
	It is not feasible to assess whether each woman received follow-up medical care since it is likely that the majority of the participants (approximately 60%) will have abnormal non-alert screening values. Therefore, programs should develop a process to determine if the referral system is working.	
	There are limitations on the use of WISEWOMAN funds for medical services beyond the baseline screening and rescreening. This information can be found in the Diagnostic Tests and Office Visits topics in this Section. Further, WISEWOMAN funds cannot be used for medication or other treatments for heart disease and stroke risk factors.	
	The WISEWOMAN Best Practices Toolkit <sup>3</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for medical referrals.	
	Note: There are specific Program requirements related to women who have alert screening values. See the Alert Values and Case Management topic in this Section for more information.	

Monitoring	CDC staff members will review minimum data elements, referral policies and procedures, training records, and other data sources to determine if the State/Tribal program is working with providers that make referrals in accordance with national clinical care and Program guidelines.	
References	<sup>1</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum. <sup>2</sup> Information about referrals for women with abnormal screening values can be found in the WISEWOMAN Screening and Referral Recommendations document which can be found in Appendix B. <sup>3</sup> The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a> . The Toolkit can be found in the Publications section on the Web page.	
Key Related Topics	Alert Values and Case Management Diagnostic Tests National Clinical Care, Diet, and Lifestyle Recommendations Office Visits	

## **Medication Access**

Requirements	WISEWOMAN funds cannot be used for treatment, including medication. Therefore, State/Tribal programs must develop a system to ensure access free or low-cost medications for women who require this augmentation to lifestyle behavior changes.  Minimum data elements <sup>1</sup> related to medication access for women with a screening values must be collected and submitted to CDC.			
Guidance	Examples of methods to ensure access to medication include, but are not limited to:  Consider how successful potential screening providers are at linking low-income clients with medication to manage chronic conditions as part of the selection process for screening providers.  Provide screening providers with a list of known patient and physician resources for discounted and free medication if the provider does not currently have a system to ensure access.  State/Tribal programs should also follow-up with the screening provider to obtain a description of the process that will be used to ensure access.  Conduct periodic audits to determine if participants who need free or low-cost medication resources were linked to these services.  Conduct periodic client surveys that include questions about medication access.  A list of potential resources follows.*  340B Drug Discount Program  http://www.hrsa.gov/opa/introduction.htm  A Health Resources and Services Administration program that gives certain Federally funded grantees access to low-cost pharmaceutical drugs.  MySimon Prescription Drugs  www.mysimon.com/category/index.jhtml?c=prescriptiondrugs  A Web site that compares the prices of pharmaceutical products available on the Web.  PhRMA Directory of Patient Assistance Programs  http://www.phrma.org/searchcures/dpdpap/  A directory of Pharmaceutical Research and Manufacturers of America members who ensure access to medicines to people who cannot afford to purchase them.			

#### **Rx** Assist

http://www.rxassist.org/default.cfm

A Web site developed by Volunteers in Health Care, a program of the Robert Wood Johnson Foundation, to provide health care practitioners with information on how to access programs that offer a limited supply of free or low-cost medications.

#### Rx Hope

https://www.rxhope.com/

A free program that helps physician's offices apply for, obtain, and track requests for no-cost medications offered by Federal, State, and charitable organizations.

#### **State Pharmaceutical Assistance Programs**

http://www.medicare.gov/spap.asp

A Web site that identifies states that have programs to provide pharmaceutical coverage or assistance, primarily to low-income older people or people with disabilities who do not qualify for Medicaid.

## **The Medicine Program**

http://www.freemedicineprogram.org/

A program that helps patients apply to pharmaceutical companies' indigent patient programs.

\* Links to non-Federal organizations in this document are provided solely as a courtesy to programs. These links do not constitute endorsements of these organizations or their programs by CDC or the Federal government, and none should be inferred. CDC is not responsible for the content of the individual organizations' Web pages found at these links.

The WISEWOMAN Best Practices Toolkit<sup>2</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for ensuring access to medication.

#### **Monitoring**

CDC staff members will review minimum data elements, policies and procedures, training records, and other data sources to determine if the State/Tribal program is working with providers that ensure access to medications.

#### References

<sup>1</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a>. Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.

<sup>2</sup> The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a>. The Toolkit can be found in the Publications section on the Web page.

## **Office Visits**

#### **Requirements**

The WISEWOMAN baseline screening must be conducted as part of the BCCEDP annual exam office visit and the WISEWOMAN rescreening must be conducted as part of the BCCEDP annual exam office visit that occurs 12-18 months after the WISEWOMAN baseline screening. That means State/Tribal WISEWOMAN programs must work with BCCEDP providers who agree to conduct BCCEDP and WISEWOMAN screening services at the same office visit. Programs that are unable to conduct these services during the same office visit must request and receive written approval from CDC to provide them at separate office visits.

WISEWOMAN Program funds can only be used to reimburse baseline, diagnostic, and rescreening office visits (for a total of no more than two offices visits per year).

Minimum data elements<sup>1</sup> related to data collected at office visits must be submitted to CDC.

Note: Rescreening can be done outside the 12-18 month time frame (from the baseline screening). However, these services must be conducted as part of the BCCEDP annual exam office visit. Rescreening may continue in subsequent years only if it is conducted as part of the BCCEDP annual exam office visit.

#### Guidance

**Baseline Screening Office Visit:** Funds may be used to pay for the time it takes to conduct the WISEWOMAN baseline screening portion of an integrated office visit (i.e., combined BCCEDP and WISEWOMAN office visit).

**Diagnostic Office Visit:** There are two scenarios for which WISEWOMAN funds may be used to reimburse a diagnostic office visit.

- 1) A woman has an abnormal non-fasting blood cholesterol or non-fasting blood glucose value at the baseline screening or rescreening and a fasting blood cholesterol or fasting blood glucose is needed to diagnose the related condition(s).
- 2) A woman has an abnormal blood pressure, fasting blood cholesterol, or fasting blood glucose clinical value at the baseline screening or rescreening and is seen at a site where the provider cannot diagnose the related condition(s).

**Rescreening Office Visits:** Funds may be used to pay for the time it takes to conduct the WISEWOMAN rescreening portion of an integrated office visit.

	The WISEWOMAN Best Practices Toolkit <sup>2</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for working with BCCEDP.	
Monitoring	CDC staff members will review policies and procedures and other data sources to determine if the State/Tribal program policies and procedures are in line with CDC WISEWOMAN Program requirements.	
References	Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.  2 The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a> . The Toolkit can be found in the Publications section on the Web page.	

## Rescreenings

## Requirements

CDC expects that all WISEWOMAN participants who return for their BCCEDP annual exam 12-18 months after their WISEWOMAN baseline screening receive WISEWOMAN rescreening services as part of their BCCEDP annual exam office visit. The rescreening includes the same assessments as the baseline screening and gives an opportunity to provide feedback to:

- 1. Women on progress made toward reaching behavioral goals and reducing their heart disease and stroke risk.
- 2. Providers on improvements made by participants and the need to reinforce lifestyle changes.
- 3. The program on the impact of its direct services.

Minimum data elements<sup>1</sup> related to rescreening measures must be collected and submitted to CDC.

#### Guidance

It is a goal of the CDC WISEWOMAN Program that State/Tribal programs provide screening and lifestyle intervention services to as many women as possible. Rescreening is a valuable service since a participant's level of heart disease and stroke risk and motivation to make lifestyle behavior changes may change over time. The WISEWOMAN Program's emphasis is on providing a rescreening for participants who return for a BCCEDP annual exam within 12-18 months of their WISEWOMAN baseline screening, but women who return outside this time frame and in subsequent years for their BCCEDP annual exam can be provided a rescreening as an effort to provide services to as many women as possible.

As stated in the Baseline Screenings topic of this document, national clinical screening guidelines recommend that clinics conduct a complete fasting lipid panel to assess for hypercholesterolemia and fasting blood glucose to assess for diabetes. While CDC also prefers this type of testing, it is recognized that some of the participants are likely to have not fasted since WISEWOMAN rescreenings are to occur during the BCCEDP screening visit. Therefore, programs are allowed to submit values for total cholesterol and HDL cholesterol using non-fasting methods. If LDL cholesterol and triglycerides are measured at the rescreening appointment, they should be done using fasting methods. For women not previously diagnosed with diabetes, programs are allowed to submit values for glucose using non-fasting methods.

Note: WISEWOMAN participants who receive a glucose test at the baseline screening and are diagnosed with diabetes as a result of their participation in the program should receive an A1C test at their rescreening appointment rather than a glucose test.

Monitoring	CDC staff members will review policies and procedures, minimum data elements, quality improvement plans, and other data sources to determine how the State/Tribal program is using its rescreening data.	
References	<sup>1</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.	
Key Related Topics	Baseline Screenings Behavior and Readiness to Change Assessments Office Visits	

## **Risk Reduction Counseling**

Requirements	Each participant must receive her baseline screening and rescreening results, interpretation of the results, and appropriate recommendations in accordance with national clinical care guidelines both in writing and verbally.	
Guidance	State/Tribal programs should decide who will provide the risk reduction counseling and when it will occur (i.e., during the baseline screening and rescreening office visit or on a different day than the office visit). Programs should take into consideration the timing of the risk reduction counseling based on the availability of blood cholesterol and blood glucose results when making this decision.	
	Programs should provide risk reduction counseling both verbally and in writing. This information should be delivered to participants in easy-to-understand and culturally appropriate language. Programs can use existing materials such as "know your numbers" which are available on the Web¹ or can develop program-specific materials to convey baseline screening and rescreening results.	
	Data analysis of previously funded WISEWOMAN programs indicates that when asked one year after the baseline screening, 46-66% of the women who had been newly diagnosed with high blood pressure, high blood cholesterol, or diabetes by the WISEWOMAN Program either said that they had not been told or they did not know if they had ever been told that they have the condition. <sup>2</sup> Therefore, programs should conduct periodic assessments with those delivering risk reduction counseling and the participants to determine if changes to the risk reduction counseling methods or materials are necessary.	
	The WISEWOMAN Best Practices Toolkit <sup>3</sup> contains examples of strategies that State/Tribal programs may want to consider when developing policies and procedures for risk reduction counseling.	
Monitoring	CDC staff members will review policies and procedures, materials that provide written feedback to participants, training records, and other data sources to determine if the State/Tribal program provides risk reduction counseling in accordance with CDC WISEWOMAN Program requirements.	

#### References

<sup>1</sup> For blood pressure "know your numbers" materials see <a href="http://hin.nhlbi.nih.gov/mission/abouthbp/numbers.htm">http://hin.nhlbi.nih.gov/mission/abouthbp/numbers.htm</a>.

For blood cholesterol "know your numbers" materials see <a href="http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.pdf">http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.pdf</a> or <a href="http://www.americanheart.org/presenter.jhtml?identifier=183">http://www.americanheart.org/presenter.jhtml?identifier=183</a>.

For blood glucose "know your numbers" materials see <a href="http://www.ndep.nih.gov/diabetes/pubs/KnowNumbers\_Eng.pdf">http://www.ndep.nih.gov/diabetes/pubs/KnowNumbers\_Eng.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Khavjou, O.A., R.K. Loo, E.A. Finkelstein, and J. Will. "Recall of Three Heart Disease Risk Factor Diagnoses Among Low Income Women." Under CDC Clearance.

<sup>&</sup>lt;sup>3</sup> The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a>. The Toolkit can be found in the Publications section on the Web page.

# Section 3 Evaluation

## **Evaluation Activities**

## Requirements

State/Tribal programs must evaluate their program to assess progress toward meeting all stated work plan objectives.

Following the guidance presented in the CDC WISEWOMAN Evaluation Overview<sup>1</sup>, State/Tribal programs will need to determine the best strategies for including the following in their program evaluation:

- Activities to assess and demonstrate the program's value, which include, but are not limited to, process and outcome evaluations; case studies; assessing public health impact; effectiveness studies; and cost-effectiveness studies.
- Assessments to determine if direct services are being implemented as intended, which include, but are not limited to, determining if the projected number of women to receive services has been met; national clinical care, diet, and physical activity recommendations are followed; and all 5 A's of the 5-A Behavioral Counseling Framework are delivered to all participants.
- Giving providers feedback using standardized process and outcome level data (e.g., data quality, changes in heart disease and stroke risk factors), CDC WISEWOMAN performance indicators, and other data sources to evaluate progress and identify processes that are working well or that need improvement.
- Using data to ensure continuous quality improvement of program services.
- Monitoring the implementation of all the core elements of the lifestyle intervention(s) to ensure it is implemented with fidelity.
- Assessing the impact of the lifestyle intervention(s).
- Logic models, flow charts, and/or algorithms that graphically describe the relationships between program activities, expected outcomes, and the data sources to be used to monitor progress.
- Plans for how lessons learned will be shared and contributions to knowledge will be made through presentations, publications, and/or other methods of dissemination. Note: At minimum, all publications and presentations using WISEWOMAN data must be reviewed by CDC staff members before they are disseminated and at least one CDC staff member must be an author on all publications.

CDC staff must review and approve all evaluation activities in writing prior to implementation. Additional written approval from CDC must be received prior to the State/Tribal program implementing changes to the originally-approved evaluation activities.

Guidance	State/Tribal programs should use the evaluation guidance presented in the CDC WISEWOMAN Evaluation Overview¹ when developing their evaluation plan.  Evaluation is defined by the CDC WISEWOMAN Program as a systematic assessment that provides useful information to document the value of the program, guide program implementation and management, demonstrate accountability, and lead to greater learning opportunities. At the very least, it should provide a solid base for decision-making that ultimately leads to a stronger and more effective program.  Programs should use program evaluation to identify areas for continuous quality improvement of program services and to ensure quality care for participants.  Programs should work with their evaluation staff to identify milestones or significant accomplishments that need to occur and performance or outcome measures for these objectives should be included in the work plan.	
	When evaluating direct services, programs should look beyond the required minimum data elements and consider questions that might be asked to help identify which activities are working well and which ones need improvement.  State/Tribal programs will work with the CDC WISEWOMAN Program to	
	determine the program's value, which includes but is not limited to, process and outcome evaluations; case studies; assessing public health impact; effectiveness studies; and cost-effectiveness studies.	
Monitoring	CDC staff members will review evidence that evaluation results are given to providers, results are used for continuous quality improvement, evaluation benchmarks are included in work plan objectives, and evaluation data are collected and reported to determine if the State/Tribal program is evaluating its WISEWOMAN program in accordance with CDC WISEWOMAN Program requirements.	
References	<sup>1</sup> The CDC WISEWOMAN Evaluation Overview can be found at <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The plan can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.	

## **Management Information System\***

Requirements	To describe the program and help monitor progress toward process and outcome measures, State/Tribal programs should use the Management Information System (MIS) to enter:  Work plan objectives and supporting activities for each awardee activity.  Baseline and target measures for each objective and the data source that will be used to determine if the objective has been met.  Actual measures and other progress information at least quarterly to track progress toward objectives.  Additional information that describes the program.	
Guidance	The program will enter data on a quarterly basis into CDC WISEWOMAN MIS to include information about staff, partnerships, the annual work plan and progress made toward achieving the objectives noted in the work plan. Data entered into MIS will be used to describe the program and monitor progress toward process and outcome measures.	
Monitoring	CDC staff members will review information entered into MIS by the State/Tribal program to determine if the State/Tribal program is making progress towards meeting work plan objectives and identify potential areas for technical assistance.	

<sup>\*</sup> Development of the WISEWOMAN MIS is on hold as of April 2008.

## **Minimum Data Elements**

## Requirements

State/Tribal programs must collect and submit minimum data elements (MDEs) to CDC or its designee semi-annually on October 15 and April 15 using a standardized format that has been established by the CDC WISEWOMAN Program.<sup>1</sup> (OMB clearance number 0920-0612)

The October 15 submission must include MDEs for services provided from June 30, 2008 through June 30 of the current year, and the April 15 submission must include MDEs for services provided from June 30, 2008 through December 31 of the previous year.

State/Tribal programs are required to use the exact MDE wording, response options, and response format as developed by the CDC WISEWOMAN Program. The assessment MDEs (Part I, Sections 4-8 that include date of assessment, personal and family health history, medication status, and smoking status) are set up as a block of questions. If State/Tribal programs choose to ask their participants additional questions not included in the assessment MDEs, those questions must be asked after all of the MDE questions. In other words, the MDE questions must be asked as a single block and the program-specific questions cannot be inserted before that block or within that block.

Cost data must be collected and submitted with the MDEs.

#### Guidance

WISEWOMAN MDEs are a set of standardized data variables developed to ensure that consistent and complete information on screening sites, participant demographic characteristics, baseline screening and rescreening results, personal and family health history, and lifestyle intervention services are collected for each participant in the WISEWOMAN Program.

State/Tribal WISEWOMAN programs should coordinate with their BCCEDP to develop a mechanism to extract WISEWOMAN MDEs already collected by BCCEDP to reduce the burden on participants and avoid duplication of efforts.

Programs must use the WISEWOMAN Data User's Manual<sup>1</sup> to design the system to collect and submit MDEs in a way that meets CDC WISEWOMAN Program requirements.

CDC staff will work with State/Tribal programs to create a system to collect cost information. This information will be used to determine cost effectiveness of the Program.

	State/Tribal programs must implement a plan to keep data confidential and that meets all Health Insurance Portability and Accountability Act (HIPAA) requirements. <sup>2</sup>	
Monitoring	EDC staff members will review bi-annual reports generated using MDEs to etermine if the State/Tribal program is collecting and submitting accurate, omplete, and timely data.	
References	<sup>1</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum. <sup>2</sup> Health Insurance Portability and Accountability Act information can be found at <a href="http://www.hhs.gov/ocr/hipaa">http://www.hhs.gov/ocr/hipaa</a> .	

## **Performance Measures**

Requirements	State/Tribal WISEWOMAN programs are expected to meet performance measures for the Program. CDC staff will identify key performance measures that will remain a priority over the entire 5-year funding period, as well as performance measures that might be high priorities for a shorter period of time (e.g., the beginning of the funding period versus the end of the funding period). <sup>1</sup>		
Guidance	CDC will use the WISEWOMAN Program performance measures as one way to assess State/Tribal program performance and progress toward meeting WISEWOMAN Program goals. CDC will use the performance measures in combination with other data sources described in the CDC WISEWOMAN Evaluation Overview to inform decision-making and Program management.  A complete set of potential performance measures can be found in the CDC		
	WISEWOMAN Evaluation Overview <sup>2</sup> . Reports on program performance will be produced by CDC routinely with feedback to State/Tribal programs at least twice each year.  A detailed explanation of the data sources and uses can be found in the CDC WISEWOMAN Evaluation Overview.		
Monitoring	CDC staff members will review reports generated using minimum data		
	elements <sup>3</sup> , policies and procedures, site visit documentation, and case study documentation to determine if the State/Tribal program is meeting performance measures,.		
	In accordance with DP08-804, the State/Tribal program's ability to complete required activities and meet CDC performance measures will be used to inform funding decisions in years 2-5.		

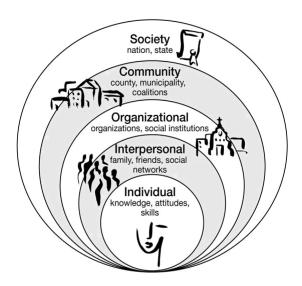
References	<sup>1</sup> Performance measure information can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The performance measure information can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.	
	<sup>2</sup> The CDC WISEWOMAN Evaluation Overview can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by CDC staff members. The document can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.	
	<sup>3</sup> Additional information about WISEWOMAN minimum data elements can be found in the WISEWOMAN Data User's Manual. The manual can be downloaded from <a href="https://team.cdc.gov/team/cdc/dispatch.cgi">https://team.cdc.gov/team/cdc/dispatch.cgi</a> . Login name and password information will be provided to programs by the CDC WISEWOMAN Program. The manual can be found in "WISEWOMAN Programs and Partners" in the "CDC Program Documents" forum.	
Key Related Topics	Minimum Data Elements	

# Section 4 Partnerships

## **Socio-Ecological Model**

## Requirements

State/Tribal programs must consider all levels of the socio-ecological model (see figure below) to identify necessary partners and strategies for conducting early detection and prevention of heart disease and stroke risk factors for women who are eligible for the WISEWOMAN Program.



At a minimum, programs must work with the following State/Tribal programs:

- BCCEDP to identify cost saving methods for recruiting eligible women, collect MDEs, and provide services.
- Tobacco control program to connect participants with free proactive quit line services and collaborate to report the number of WISEWOMAN participants who use these services.
- Heart disease and stroke prevention program or coalition to increase knowledge of signs and symptoms for heart disease and stroke and the importance of calling 9-1-1.
- Those that can impact policies and environments where WISEWOMAN participants live, work, and play.

#### Guidance

Programs should provide evidence that they are working with partners and have identified strategies that will support heart healthy behaviors for women who are eligible for the WISEWOMAN Program. Evidence includes, but is not limited to, the work plan, meeting minutes, and sources used for the non-Federal match.

Examples of collaboration might include, but are not limited to, working with:

- Individuals who have expertise in the detection, evaluation, and treatment of heart disease and stroke risk factors; diet and lifestyle counseling or health education; and community planning and/or knowledge of existing community-based resources that support the adoption and maintenance of heart healthy behaviors to:
  - a. Determine appropriate direction of the program and identify appropriate strategies for implementing all program activities.
  - b. Develop policies and procedures.
  - c. Create culturally appropriate program materials and messages that can be delivered in easy-to-understand language for the intended audience.
  - d. Provide development opportunities related to prevention, detection, and treatment of heart disease and stroke risk factors.
- State nutritionists, physical activity interventionists, State Fruits & Veggies—More Matters coordinator and/or staff of the Nutrition and Physical Activity to Prevent Obesity and Other Chronic Diseases program to ensure consistent messages.
- Organizations or programs to create system, organizational, and environmental changes that support a heart healthy lifestyle.
- State and local groups/organizations to create supportive environments that include safe and walkable communities, available low-cost heart healthy foods, and farmer's markets in neighborhoods where WISEWOMAN participants live, work, and play.
- State-based or other Diabetes Prevention and Control Programs to identify low-cost diabetes education resources.
- Office of Women's Health and Office of Minority Health to identify culturally-relevant resources and other agencies that serve racial and ethnic minority women.
- Other chronic disease programs to be sure WISEWOMAN goals are reflected in State/Tribal action plans that address chronic disease prevention.
- Local community organizations to create or provide access to lowcost resources and activities that promote heart healthy behaviors.

	Examples of part model are:	ners and strategies at each level of the socio-ecological
	Individual	Work with screening providers and lifestyle interventionists to provide direct services.
	Interpersonal	Work with university outreach and extension staff to provide group lifestyle intervention classes that allow family and friends to attend.
	Organizational	Work with provider clinic sites to help them adopt national clinical care, diet, and lifestyle recommendations.
	Community	Work with an organization on policies or environmental changes that support heart health (e.g., policies for schools to keep their gymnasiums open in the evening or on weekends for community use).
	Society	Work with state or national organizations to support heart health (e.g., resources for statewide heart disease and stroke awareness campaigns).
	that State/Tribal	AN Best Practices Toolkit <sup>1</sup> contains examples of strategies programs may want to consider when thinking through I levels of the socio-ecological model.
Monitoring	CDC staff members will review the work plan, progress reports, sources of non-Federal match, memorandums of understanding, and other data sources to determine if the State/Tribal program is working with partners to impact all levels of the socio-ecological model.	
References	<sup>1</sup> The WISEWOMAN Best Practices Toolkit can be downloaded from <a href="http://www.cdc.gov/wisewoman/">http://www.cdc.gov/wisewoman/</a> . The Toolkit can be found in the Publications section on the Web page.	

## **Tobacco Cessation Resources**

Requirements	State/Tribal WISEWOMAN programs must work with the State/Tribal tobacco control program to connect participants with free proactive quit line services and report the number of WISEWOMAN participants who use these services.
Guidance	State/Tribal programs must ensure that screening and lifestyle intervention providers know when and how to link participants to the State/Tribal proactive tobacco quit line or other community-based tobacco cessation resources, as appropriate.
	Programs need to work with the State/Tribal tobacco proactive quit line or other tobacco cessation programs and collaborate to report the number of women who use these services.
	If the State/Tribal quit line is not equipped to address language and other cultural barriers of WISEWOMAN participants, then WISEWOMAN program staff members should collaborate with the State/Tribal tobacco control program and other organizations that address tobacco use (e.g., American Lung Association, American Heart Association, American Cancer Society) to identify or develop alternative free or low-cost tobacco cessation strategies or resources. This might include private quit line services, Web-based self-help cessation programs, or training community members to provide tobacco cessation counseling.
	Note: WISEWOMAN funds cannot be used for nicotine replacement therapies. Because free tobacco cessation resources are widely available, WISEWOMAN funds should not be used to pay for tobacco cessation services.
Monitoring	CDC staff members will review policies and procedures, progress reports, documentation of available cessation resources, and other data sources to determine if the State/Tribal program has a process in place to connect participants with tobacco cessation resources.

# Appendices

# Appendix A

# The Process for Approval of WISEWOMAN-funded Lifestyle Interventions

It is the CDC WISEWOMAN Program's goal to reduce burden on funded programs as much as possible and expedite the Lifestyle Intervention (LSI) approval process. The following will apply to all requests for approval of WISEWOMAN-funded LSIs:

- 1. All requests for LSI approval should be made by e-mail to your Project Officer (PO).
- 2. Your PO will involve other CDC WISEWOMAN team members/contractors as appropriate. For consistency, a CDC WISEWOMAN team member has been assigned to be the lead on each LSI that has a template on www.wiseinterventions.org.
- 3. Within 48 hours after your initial request, your PO will send you an e-mail indicating the date by which you will receive approval.
- 4. If your PO is out of the office for an extended period of time, an alternative contact will be provided to you in her absence.
- 5. It is the CDC WISEWOMAN Program's goal to have written approval sent by e-mail to you within 7-10 business days of the request.

Keep in mind that if you plan to use more than one WISEWOMAN-funded LSI, you will be required to receive approval for each of them before implementation can begin.

#### What is Needed for Approval of WISEWOMAN-Funded LSIs

- A. If you are using an LSI that has been reviewed and approved by CDC as it is described on <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> with <a href="https://www.wiseinterventions.org">all</a> the core elements being delivered as intended:
  - Talk to your PO about the LSI you intend to use.
  - Let your PO know that you plan to use the LSI exactly as described in the template on <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> with no changes to the content of the materials or how it will be delivered. Your PO will let you know if she needs to review any of your materials but you will <a href="https://not.need.org/need.org/">not need to recreate the template</a>.
  - If you need to modify any of the materials or modes of delivery to fit your local context, submit those materials to your PO by e-mail with a summary of what was changed. Keep in mind that you are allowed to make adaptations to fit your local context as long as in doing so, you maintain all the core elements of the LSI.
    - 1. Example: In *A New Leaf...Choices for Healthy Living*, one of the core elements is, "Assessments of Diet, Physical Activity, and Smoking". That means you must do assessments of all three (diet, physical activity, and smoking) or you are no longer doing *A New Leaf.* You can, however, make changes to the assessment questions to fit your local context (e.g., use collard greens as an example in the diet assessment rather than fish, give skiing as an example for physical activity rather than biking).
    - 2. Example: In *Health Partnership*, one of the core elements is, "Follow-up". The description says, "Consistent follow-up with the client by the Lifestyle Counselor is important to establish/build rapport." In the "How it Works" section of the template, it indicates that there are 2-5 contacts and they are delivered either face-to-face (individual or group) or by telephone. An example of an acceptable adaptation that keeps the core element intact would be to have 2 contacts for women with few risk factors and high motivation and 4 contacts for

women with multiple risk factors and high motivation and to have those follow-up contacts only occur by telephone.

## B. If you are using an LSI that has been reviewed and approved by CDC as it is described on <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> as the foundation for your LSI but are <a href="mailto:changing one or more core">changing one or more core</a> elements:

- Talk to your PO about the LSI you intend to use as the foundation for your LSI and what core element(s) you plan to change.
- Submit the following using the intervention template on <u>www.wiseinterventions.org</u>:
  - 1. A description of the underlying theories of the LSI.
  - 2. A step-by-step description of the evidence-based strategies of the LSI.
  - 3. A summary of the results of the evidence reviewed.
  - 4. A list of the core elements, which are the elements of the LSI that are central to its theory and logic and that are thought to be responsible for its effectiveness. These core elements cannot be changed when the LSI is implemented or adapted. For an example of what will need to be submitted to CDC, go to <a href="www.wiseinterventions.org">www.wiseinterventions.org</a> to review the approved intervention templates.
- You will need to justify the changes with evidence, not just logic. Refer to the templates on <a href="https://www.wiseinterventions.org">www.wiseinterventions.org</a> to see the type of evidence needed to justify an approach/strategy.
- You may also decide to pilot test a change you want to make and provide the evaluation results as evidence to support the change. Talk to your PO about the documentation you will need to provide in order for the change to be considered for approval.
- For the parts of the LSI you are not changing, you can use evidence and descriptions from the template of the LSI you are using as your foundation.

## C. If you are using an LSI that has <u>not</u> been reviewed and approved by CDC:

- Talk to your PO about the LSI you intend to use.
- Discussions will occur with your PO and others on the CDC WISEWOMAN team to help you identify the best approach for documenting all that is required for your LSI to be approved.
- Submit the following using the intervention template on www.wiseinterventions.org:
  - 1. A description of the underlying theories of the LSI.
  - 2. A step-by-step description of the evidence-based strategies of the LSI.
  - 3. A summary of the results of the evidence reviewed.
  - 4. A list of the core elements, which are the elements of the LSI that are central to its theory and logic and that are thought to be responsible for its effectiveness. These core elements cannot be changed when the LSI is implemented or adapted. For an example of what will need to be submitted to CDC, go to <a href="www.wiseinterventions.org">www.wiseinterventions.org</a> to review the approved intervention templates.

Source: The information in Appendix A is based on guidance sent in an e-mail to funded programs on June 23, 2008.

# Appendix B

## WISEWOMAN Screening and Referral Recommendations

The following table represents the measurements that at minimum are expected to be done on all WISEWOMAN participants at the baseline screening and rescreening appointments. Since the WISEWOMAN screening services are expected to be integrated into the BCCEDP annual exam appointment, it is not always practical to require the women to fast prior to the appointment. Women who have abnormal non-fasting values for blood cholesterol or glucose are expected to be referred for diagnostic tests in accordance with national clinical care guidelines.

Measurement	Normal/ Desirable	Abnormal					
Blood Pressure (mmHg)	<120 Systolic <i>and</i> <80 Diastolic	Prehypertension 120-139 Systolic or 80-89 Diastolic	Stage 1 Hypertension 140-159 Systolic or 90-99 Diastolic	Stage 2 Hypertension ≥160 Systolic or ≥100 Diastolic	Alert* >180 Systolic or >110 Diastolic		
Total Cholesterol (mg/dL)	<200	Borderline-high 200-239	<u><b>High</b></u> ≥240		<u>Alert</u> * >400		
HDL Cholesterol (mg/dL)	40-59 ≥60 (High)	<u>Low</u> <40					
Blood Glucose (Casual) (mg/dl)	<200 with no symptoms	<u>Diabetes</u> ≥200 plus symptoms			<u>Alert</u> * >375		
Height and Weight – Body Mass Index (BMI kg/m²)	18.5-24.9	Overweight 25-29.9	Obesity (Class 1) 30-34.9	Obesity (Class 2) 35-39.9	Extreme obesity (Class 3) >40		

The following table represents the additional measurements taken at the baseline screening and rescreening appointments when women have fasted.

Measurement	Normal/ Desirable	Abnormal				
LDL Cholesterol (mg/dL)	<b>Optimal</b> <100	Near Optimal/ Above Optimal 100-129	Borderline High 130-159	High 160-189	Very High ≥190	
Triglycerides (mg/dL)	<150	Borderline-high 150-199	High 200-499	Very High ≥500		
Blood Glucose (mg/dl)	FPG <100 OGTT <140	Prediabetes FPG 100-125 OGTT 140-199	Diabetes FPG ≥126 OGTT ≥200		<u>Alert</u> * >375	

<sup>\*</sup> NHANES and NHLBI recommendations were used to identify alert values for the WISEWOMAN Program. Women with alert values should be evaluated and treated immediately or within 1 week, depending on the clinical situation and complications, in accordance with national and Program guidelines.

Note: WISEWOMAN funds cannot be used for treatment, including medication.